108TH CONGRESS
1ST SESSION

S. 51

To provide access and choice for use of generic drugs instead of nongeneric drugs under Federal health care programs, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JANUARY 7, 2003

Mr. JOHNSON introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To provide access and choice for use of generic drugs instead of nongeneric drugs under Federal health care programs, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Generic Pharmaceutical Access and Choice for Consumers Act of 2003''.

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

SEC. 2. FINDINGS AND PURPOSES.

(a) FINDINGS.—Congress makes the following findings:

(1) Generic pharmaceuticals are approved by the Food and Drug Administration on the basis of scientific testing and other information establishing that such pharmaceuticals are therapeutically equivalent to brand-name pharmaceuticals, ensuring consumers a safe, efficacious, and cost-effective alternative to brand-name innovator pharmaceuticals.

(2) The pharmaceutical market has become increasingly competitive during the last decade because of the increasing availability and accessibility of generic pharmaceuticals.

(3) The Congressional Budget Office estimates that—

(A) the substitution of generic pharmaceuticals for brand-name pharmaceuticals will save purchasers of pharmaceuticals between $8,000,000,000 and $10,000,000,000 each year; and

(B) quality generic pharmaceuticals cost between 25 percent and 60 percent less than brand-name pharmaceuticals, resulting in an estimated average savings of $15 to $30 on each prescription filled.

(4) Independent studies have estimated that generics provide an average savings of $45.50 for each prescription drug sold.

(5) Generic pharmaceuticals are widely accepted by both consumers and the medical profession, as the market share held by generic pharmaceuticals compared to brand-name pharmaceuticals has more than doubled during the last decade, from approximately 19 percent to 43 percent, according to the Congressional Budget Office.

(6) Generic pharmaceuticals can save consumers an additional $1,320,000,000 each year for each 1 percent increase in the use of such pharmaceuticals.

(7) Generic pharmaceutical use can help both consumers and the Government reduce the cost of prescription drugs.

(b) PURPOSES.—The purposes of this Act are—

(1) to reduce the cost of prescription drugs to the United States Government and to beneficiaries under Federal health care programs while maintaining the quality of health care by requiring the use of generic drugs rather than nongeneric drugs, unless no therapeutically equivalent generic drug has been approved under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or the nongeneric drug is specifically—

(A) ordered by the prescribing provider; or

(B) requested by the individual for whom the drug is prescribed; and

(2) to increase the utilization of generic pharmaceuticals by requiring the Food and Drug Administration, where appropriate, to determine that a generic pharmaceutical is the therapeutic equivalent of its brand-name counterpart, and by affording national uniformity to that determination.

TITLE I—REQUIRING THE USE OF GENERIC DRUGS

SEC. 101. REQUIRING THE USE OF GENERIC DRUGS UNDER THE PUBLIC HEALTH SERVICE ACT.

(a) IN GENERAL.—Part B of title II of the Public Health Service Act (42 U.S.C. 238 et seq.) is amended by adding at the end the following new section:

"SEC. 249. USE OF GENERIC DRUGS REQUIRED.

''(a) REQUIREMENT.—Each grant or contract entered into under this Act that involves the provision of health care items or services to individuals shall include provisions to ensure that any prescription drug provided for under such grant or contract is filled by providing the generic form of the drug involved, unless no generic form of the drug has been approved under the Federal Food, Drug, and Cosmetic Act or the nongeneric form of the drug is specifically—

''(1) ordered by the prescribing provider; or

''(2) requested by the individual for whom the drug is prescribed.

''(b) DEFINITIONS.—In this section:

''(1) GENERIC FORM OF THE DRUG.—The term 'generic form of the drug' means a drug that is the subject of an application approved under subsection (b)(2) or (j) of section 505 of the Federal Food,

Drug, and Cosmetic Act (21 U.S.C. 355), for which the Secretary has made a determination that the drug is the therapeutic equivalent of a listed drug under section 505(o) of that Act (21 U.S.C. 355(o)).

''(2) NONGENERIC FORM OF THE DRUG.—The term 'nongeneric form of the drug' means a drug that is the subject of an application approved under—

''(A) section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(1)); or

''(B) section 505(b)(2) of such Act and that has been determined to be not therapeutically equivalent to any listed drug.

''(3) PRESCRIPTION DRUG.—The term 'prescription drug' means a drug that is subject to the provisions of section 503(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)).''.

(b) EFFECTIVE DATE.—The amendment made by this section shall apply with respect to any drug furnished on or after the date of enactment of this Act.

SEC. 102. APPLICATION TO FEDERAL EMPLOYEES HEALTH BENEFITS PROGRAM.

(a) IN GENERAL.—Section 8902 of title 5, United States Code, is amended by adding at the end the following new subsection:

''(p) If a contract under this chapter provides for the provision of, the payment for, or the reimbursement of the cost of any prescription drug (as defined in paragraph (3) of section 249(b) of the Public Health Service Act), the carrier shall provide, pay, or reimburse the cost of the generic form of the drug (as defined in paragraph (1) of such section), except that this subsection shall not apply if the nongeneric form of the drug (as defined in paragraph (2) of such section) is specifically—

''(1) ordered by the prescribing provider; or

''(2) requested by the individual for whom the drug is prescribed.''.

(b) EFFECTIVE DATE.—The amendment made by this section shall apply to any prescription drug furnished during contract years beginning on or after January 1, 2004.

SEC. 103. APPLICATION TO MEDICARE PROGRAM.

(a) IN GENERAL.—Section 1861(t) of the Social Security Act (42 U.S.C. 1395x(t)) is amended by adding at the end the following new paragraph:

''(3) For purposes of paragraph (1), the term 'drugs' means the generic form of the drug (as defined in section 249(b)(1) of the Public Health Service Act), unless no generic form of the drug has been approved under the Federal Food, Drug, and Cosmetic Act or the nongeneric form of such drug (as defined in section 249(b)(2) of such Act) is specifically—

''(A) ordered by the health care provider; or

''(B) requested by the individual to whom the drug is provided.''.

(b) EFFECTIVE DATE.—

(1) IN GENERAL.—Except as provided in paragraph (2), the amendment made by this section shall apply with respect to any prescription drug furnished on or after the date of enactment of this Act.

(2) MEDICARE+CHOICE PLANS.—In the case of a Medicare+Choice plan offered by a Medicare+Choice organization under part C of title XVIII of the Social Security Act (42 U.S.C. 1395w–21 et seq.), the amendment made by this section shall apply to any prescription drug furnished during contract years beginning on or after January 1, 2004.

SEC. 104. APPLICATION TO MEDICAID PROGRAM.

(a) IN GENERAL.—Section 1902(a) of the Social Security Act (42 U.S.C. 1396a(a)) is amended—

(1) in paragraph (64), by striking ''and'' at the end;

(2) in paragraph (65), by striking the period at the end and inserting ''; and''; and

(3) by adding the following new paragraph:

''(66) provide that the State shall, in conjunction with the program established under section 1927(g), provide for the use of a generic form of a drug (as defined in paragraph (1) of section 249(b) of the Public Health Service Act), unless no generic form of the drug has been approved under the Federal Food, Drug, and Cosmetic Act or the non-generic form of the drug (as defined in paragraph (2) of such section) is specifically—

''(A) ordered by the provider; or

''(B) requested by the individual to whom the drug is provided.''.

(b) EFFECTIVE DATE.—The amendment made by this section shall apply with respect to any prescription drug furnished under State plans that are approved or renewed on or after the date of enactment of this Act.

SEC. 105. APPLICATION TO INDIAN HEALTH SERVICE.

(a) IN GENERAL.—Title II of the Indian Health Care Improvement Act (25 U.S.C. 1621 et seq.) is amended—

(1) by redesignating sections 224 and 225 as sections 225 and 226, respectively; and

(2) by inserting after section 223 the following new section:

"SEC. 224. USE OF GENERIC DRUGS REQUIRED.

''In providing health care items or services under this Act, the Indian Health Service shall ensure that any prescription drug (as defined in paragraph (3) of section 249(b) of the Public Health Service Act) that is provided under this Act is the generic form of the drug (as defined in paragraph (1) of such section) involved, unless no generic form of the drug has been approved under the Federal Food, Drug, and Cosmetic Act or the nongeneric form of the drug (as defined in paragraph (2) of such section) is specifically—

''(1) ordered by the prescribing provider; or

''(2) requested by the individual for whom the drug is prescribed.''.

(b) EFFECTIVE DATE.—The amendment made by this section shall apply with respect to any prescription drug furnished on or after the date of enactment of this Act.

SEC. 106. APPLICATION TO VETERANS PROGRAMS.

(a) USE OF GENERIC DRUGS REQUIRED.—Subchapter III of chapter 17 of title 38, United States Code, is amended by inserting after section 1722A the following new section:

"§ 1722B. Use of generic drugs required

"When furnishing a prescription drug (as defined in paragraph (3) of section 249(b) of the Public Health Service Act) under this chapter, the Secretary shall furnish a generic form of the drug (as defined in paragraph (1) of such section), unless no generic form of the drug has been approved under the Federal Food, Drug, and Cosmetic Act or the nongeneric form of the drug (as defined in paragraph (2) of such section) is specifically—

"(1) ordered by the prescribing provider; or

"(2) requested by the individual for whom the drug is prescribed.".

(b) CLERICAL AMENDMENT.—The table of sections at the beginning of chapter 17 of such title is amended by inserting after the item relating to section 1722A the following new item:

"1722B. Use of generic drugs required.".

(c) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to any prescription drug furnished on or after the date of enactment of this Act.

SEC. 107. APPLICATION TO RECIPIENTS OF UNIFORMED SERVICES HEALTH CARE.

(a) USE OF GENERIC DRUGS REQUIRED.—Chapter 55 of title 10, United States Code, is amended by adding at the end the following new section:

"§ 1111. Use of generic drugs required

''The Secretary of Defense shall ensure that each health care provider who furnishes a prescription drug (as defined in paragraph (3) of section 249(b) of the Public Health Service Act) furnishes the generic form of the drug (as defined in paragraph (1) of such section), unless no generic form of the drug has been approved under the Federal Food, Drug, and Cosmetic Act or the nongeneric form of the drug (as defined in paragraph (2) of such section) is specifically—

''(1) ordered by the prescribing provider; or

''(2) requested by the individual for whom the drug is prescribed.''.

(b) CLERICAL AMENDMENT.—The table of sections at the beginning of such chapter is amended by inserting after the item relating to section 1110 the following new item:

''1111. Use of generic drugs required.''.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to any drug furnished on or after the date of enactment of this Act.

SEC. 108. APPLICATION TO FEDERAL PRISONERS.

(a) IN GENERAL.—Section 4006(b) of title 18, United States Code, is amended by adding at the end the following new paragraph:

''(3) USE OF GENERIC DRUGS REQUIRED.—The Attorney General shall ensure that each health care provider who furnishes a prescription drug (as defined in paragraph (3) of section 249(b) of the Public Health Service Act) to a prisoner charged with or convicted of an offense against the United States furnishes the generic form of the drug (as defined in paragraph (1) of such section), unless no generic form of the drug has been approved under the Federal Food, Drug, and Cosmetic Act or the non-generic form of the drug (as defined in paragraph (2) of such section) is specifically—

''(A) ordered by the prescribing provider; or

''(B) requested by the prisoner for whom the drug is prescribed.''.

(b) EFFECTIVE DATE.—The amendment made by this section shall apply with respect to any prescription drug furnished on or after the date of enactment of this Act.

TITLE II—THERAPEUTIC EQUIVALENCE REQUIREMENTS FOR GENERIC DRUGS

SEC. 201. THERAPEUTIC EQUIVALENCE OF GENERIC DRUGS.

(a) IN GENERAL.—Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended—

(1) by adding at the end the following new subsection:

''(o)(1) For each application filed under subsection (b)(2) or subsection (j), the Secretary shall determine whether the drug for which the application is filed is the therapeutic equivalent of the drug for which the investigations have been made under subsection (b)(1)(A) (in this subsection referred to as the 'reference drug') or the listed drug referred to in subsection (j)(2)(A)(i). For applications approved after the date of enactment of this subsection, the Secretary's determination shall be made before the approval of the application. For such applications approved before such date, the most recent determination made by the Secretary shall be confirmed.

''(2) For purposes of paragraph (1), a drug is the therapeutic equivalent of a reference drug or a listed drug if—

''(A) each active ingredient of the drug and either the reference drug or the listed drug is the same;

''(B) the drug and either the reference drug or the listed drug—

''(i) are of the same dosage form;

''(ii) have the same route of administration;

''(iii) are identical in strength or concentration; and

''(iv) are expected to have the same clinical effect and safety profile when administered to patients under conditions specified in the labeling; and

''(C) the drug does not present a known bioequivalence problem, or if the drug presents such a problem, the drug is shown to meet an appropriate bioequivalence standard.

''(3) With respect to a drug for which a therapeutic equivalence determination has been made or confirmed under this subsection, no State or political subdivision of a State may establish or continue in effect with respect to therapeutic equivalence of the drug to either a reference drug or a listed drug, any requirement which is different from, or in addition to, or is otherwise not identical with,

the Secretary's determination or confirmation under this subsection.''; and

(2) in subsection (j)(7)(A), by adding at the end the following new clause:

''(iv) The Secretary shall include in each revision of the list under clause (ii) on or after the date of enactment of this clause the official and proprietary name of each reference drug or listed drug that is therapeutically equivalent to a drug approved under subsection (b)(2) or under this subsection during the preceding 30-day period, as determined under subsection (o).''.

(b) EFFECTIVE DATE.—The amendments made by this section shall take effect on the date of enactment of this Act.

TITLE III—GENERIC PHARMACEUTICALS AND MEDICARE REFORM

SEC. 301. SENSE OF THE SENATE ON REQUIRING THE USE OF GENERIC PHARMACEUTICALS UNDER THE MEDICARE PROGRAM.

It is the sense of the Senate that legislative language requiring the safe and cost-effective use of generic pharmaceuticals should be considered in conjunction with any legislation that adds a comprehensive prescription drug

benefit to the medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.).

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